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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,412	06/12/2000	GUNTHER SCHNEIDER	BEIERSDORF6	9863

7590 08/26/2004
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EXAMINER

YU, GINA C

ART UNIT PAPER NUMBER

1617

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/581,412

Applicant(s)

SCHNEIDER ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 25, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-17, 19-36, 38-40 and 44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-17, 19-36, 38-40 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 25, 2004 has been entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 11-17, 19-36, 38-40, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackman et al. (US 6,352,998 B2) ("Jackman") in view of Schneider et al. (US 5780445) ("Schneider") and Aronson et al. (US 4,606,913) ("Aronson").

Jackman teaches topical pharmaceutical compositions. The reference teaches that the preferred emulsifiers include glycerine monostearate, sorbitan mono stearate (Arlacel 60), sorbitan mono oleate, glycerine mono stearate (Imwitor 960), cetyl alcohol, and mixture thereof. See col. 5, lines 50 – 60. Examples 1 and 2 show O/W emulsions, each comprising oleyl alcohol, cetyl alcohol, stearyl alcohol, sorbitan monostearate, and glycerine mono stearate. Example 17 comprises 3 % of sorbitan monostearate and 10.5 % of oleyl, cetyl, and stearyl alcohols. See instant claims 14, 15, 19, 33, 34. As for claims 16, 17, 35, and 36, differences in concentration ordinarily will not support the

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patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. The reference teaches in col. 5, lines 50 – 60 to use 1-30 % of emulsifiers. Since the general conditions of emulsifier concentration is disclosed in Jackman, examiner views that one having ordinary skill in the art would have discovered the optimum or workable ranges of the emulsifiers by routine experimentation to achieve the stability of the emulsion.

The reference fails to teach element 11(i), one or more partially neutralized esters of monoglycerides and/or diglycerides of saturated fatty acids with citric acid.

Schneider teaches in Examples 10 and 11, O/W topical emulsions comprising 1 and 2 % by weight of glyceryl stearate citrate, respectively. See instant claims 12, 13, 21, 23, 32, 33, and 40. See also instant claims 19, 20, 38, and 39.

Jackman and Schneider fail to teach electrolyte dissolved in the aqueous phase.

Aronson teaches that the concept of achieving increased stability of an emulsion by adding electrolytes in its aqueous phase and by further incorporating conventional emulsifiers well known in the art. The reference teaches a topical emulsion composition with electrolyte in aqueous phase. See instant claims 22, 24. The reference further teaches that the incorporation of sufficient amount of electrolyte into the aqueous phase of the emulsion results in the improved stability of the emulsion, i.e., reduced chance of phase separation for extended periods of time. The stability of the emulsions is described in detail in col. 19, lines 21 – 57. The reference teaches using about 0.001 to about 10 % by weight of the electrolytes. See col. 8, line 67 – col. 9, line 8. See instant claims 25-30. The Aronson reference is directed to a high internal phase emulsion, and

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teaches using emulsifiers in the amount of 0.5 to 5 % by weight of the emulsion. See col. 6, lines 8-17. The reference teaches organic electrolytes including salts of carboxylic acids. See col. 9, line 61 – col. 10, lines 20. Lactates and glycolates are particularly mentioned. See instant claim 44.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Jackman by adding glyceryl stearate citrate as motivated by Schneider because of the expectation of successfully producing a stable topical O/W emulsion. It would have been also obvious to the skilled artisan to have further incorporated electrolytes to the aqueous phase of the emulsion as motivated by Aronson because of the expectation of successfully achieve improved stability of the emulsion.

Response to Arguments

Applicant's arguments with respect to claims 11-17, 19-36, 38-40, and 44 have been considered but are moot in view of the new ground(s) of rejection in part and unpersuasive in part.

Applicants assert that the stability of the emulsion cannot be a parameter in routine optimization of the amount of the emulsifiers. Examiner respectfully disagrees. The references expressly disclose that emulsifiers and electrolytes are used to achieve stability of the emulsion and to prevent the phase separation. Applicants' statement that recognizing this parameter would mean that "any composition that achieves this result [stability] would be non-patentable over the reference" is not agreed. Examiner's rationale is applied in this particular invention because the claims recite to use the

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emulsifiers and electrolytes that are well known in cosmetic emulsion art within the obvious weight range taught by the prior arts. In fact, the Aronson invention is directed to the method of stabilizing an emulsion by incorporating electrolytes in the aqueous phase of the emulsion. The statement that the optimization would require "simple experiments" is not an examiner's inventive word but found from the prior art. See col. 8, lines 54 – 65; col. 9, lines 19 – 24.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner



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